

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2 and 4-7 are again rejected under 35 U.S.C. 112, first paragraph, because the specification, does not reasonably provide enablement for a -X-Z-Y- substituent with X and Y being heteroatom, heteroatom-containing group or heterocycle, Z being a divalent radical.

Applicants' comments have been noted and considered but are not deemed persuasive of patentability.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims. In these claims, the numerous variables (e.g. X, Y, Z, J, R', R'', heteroatoms, heteroatom-containing groups, heterocycle etc.) and their voluminous complex meanings and their seemingly endless permutations and combinations are not adequately enabled.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 ('Fed. Cir. 1988).

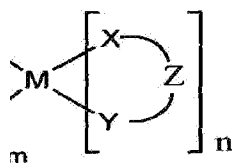
There are many factors to be considered when determining whether there is sufficient

evidence to support a determination that a disclosure does not satisfy the enablement requirement

and whether any necessary experimentation is undue". These factors include

- 1) the breadth of the claims,
- 2) the nature of the invention,
- 3) the state of the prior art,
- 4) the level of one of ordinary skill,
- 5) the level of predictability in the art,
- 6) the amount of direction provided by the inventor,
- 7) the existence of working examples, and
- 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The breadth of the claims with respect to the X-Z-Y- substituent alone



Includes heteroatoms S, O, N and P, heteroatom-containing groups OR, SR, NR<sub>2</sub> and PR<sub>2</sub> or heterocycle substituents.

The specification only has support for, e.g., pyrazoles, triazoles, tetrazoles, thiazoles, furans and pyridines.

The nature of the invention is a cyclometalated complex compound wherein the X-Z-Y- substituent, according to the specification page 18 paragraph 00053, can only be are heterocycles selected to have functionality appropriate for coordinating to M.

The level of skill and predictability in the art would require, for example, that every known heterocycle be tested in order to determine which heterocycles would have functionality appropriate for coordinating to M.

The direction provided by applicants only support pyrazoles, triazoles, tetrazoles, thiazoles, furans and pyridines heterocycle substituents.

There are no working examples for any others.

The unclear definition of the X-Z-Y- substituent requires an undue amount of experimentation to practice the invention. The general terms of having a heteroatom, heteroatom-containing group or heterocycle, divalent linker gives rise to numerous permutations and combinations of hetero groups.

There is insufficient disclosure of starting materials that would place such a diverse genus of compounds in possession of the public in the event of a patent grant. In addition, there is no reasonable assurance that such an alleged genus of compounds would possess all of the alleged properties for use. See *In re Fouche* 169 USPQ 429 ((CCPA 1971)). Quite clearly, more than routine experimentation would be required to place the claimed compounds, compositions and methods of use in possession of the public in the event of a patent grant. See *In re Armbruster*, 185 USPQ 152 (CCPA 1975).

Regarding applicants' comments it is noted that the specification only supports pyrazole X-Y-Z groups. See pages 21,22, 28, 29, 30, 32 and 27 which defines the "pz" in the table on page 32.

The amendment of 1/7/08 while more specifically defining the heteroatoms of the heterocyclic rings does not overcome the rejection for the reasons of record. The scope of the claims is essentially unchanged.

The numerous substituent variables and their voluminous complex meanings and their seemingly endless permutations and combinations make it virtually impossible to determine the full scope and complete meaning of the claimed subject matter. As presented, the subject matter cannot be regarded as being a clear and concise description for which protection is sought and as such the listed claims are indefinite.

It is recognized that it is not required that every compound under the generic claims be exemplified. However, the generic description together with the four examples disclosed in applicants' specification would not place the organometallic compounds of formula (I) in possession by the skilled artisan in the field. There is no reasonable basis for assuming that the myriad of compounds embraced by the claims, including, e.g. 3 to 7 membered heterocyclic rings containing at least one

heteroatom, will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent.

The specification only provides some examples of what these terms may signify, but does not limit "heterocyclic" to any particular definition. For example, page 26 paragraph [00076] teach many examples of "heterocyclic groups," but this section specifically notes that the definition includes but is not limited to the examples set forth therein. So it is clear that applicants do not wish to be limited to only those named heterocycles. However, the specification does not provide enablement as to how to make the vast number of compounds encompassed by the scope of the recitation. On page 490 of the Concise Encyclopedia Chemistry, the definition of "heterocycles" is cyclic hydrocarbon compounds in which the ring consists of carbon and at least one other element, usually, N, O or S. The definition goes on to explain that the possibilities for synthesis are nearly unlimited.

Claims 8, 13 and 15 are objected to as depending from a rejected base claim but would be allowable if presented in independent form.

No claim is allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (571) 272-0681. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres at telephone number (571) 272-0867.

The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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